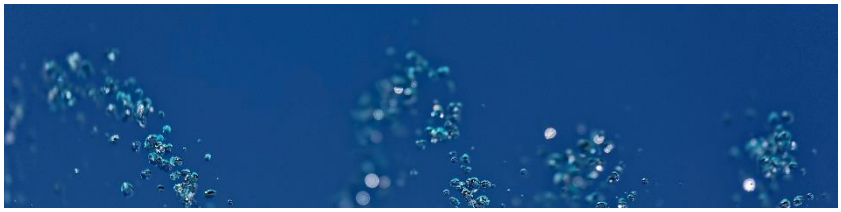
Friday, 19th July 2019

EMVO NEWSLETTER

European Medicines Verification Organisation

What's new at EMVO:

NMVO Update



This week's NMVO contribution comes from Katriina Newton-Kolehmainen, Communications Assistant at **FimVO, the Finnish Medicines Verification Organisation** who shares with us an insight the situation on Finland.

FiMVO was up and ready come the 9th February deadline, after having been live in Finland for a few months already. We were prepared for the worst but were in for a smoother ride than we had dared hope for.

The use of medicines verification worked well throughout the spring and into summer. The number of packs in the system is increasing all the time, the accuracy of the data improving, and the errors by the users are reducing.

We hold a few workshops a year for our end users and MAHs, and in June we focused on urging everyone to step up in order to reach a sufficiently low level of alerts. We need to invest in this now, because we have planned the end of our soft launch of the system for the end of September.

The number of alerts is stabilizing but will only fall to an acceptable level after every last cog in the wheel is oiled.

We have found the most common user related false alerts stem from failed scanning of the 2D matrix. There may be characters missing, or the barcode scanner changes capital letters to small letters, or vice versa. We're constantly working with the End User software suppliers in order to get these issues fixed.

Our message to manufacturers is to pay attention to the following issues:

- Expiry date printed on packs should match the expiry date encoded in the 2D matrix and the information uploaded to FiMVS.

- We recommend placing the 2D data matrix on another side of the pack to the linear barcode if the EAN code is still needed on the pack. Ideally it would be best to remove the EAN code completely.

- The supply chain should be notified of the first serialized batch in Finland, paying special attention to expiry date matches.

- FiMVO must be informed of non-EU serialized batches so that they can be placed on a list that will prevent them from being scanned and causing unnecessary alerts.

- If you have a multimarket pack, you must upload the data in all the target country systems.

The autumn will bring fresh challenges and we are ready for them!

For more information on FiMVO visit our **website** and follow us on **LinkedIn**.

Katriina Newton-Kolehmainen

Communications Assistant

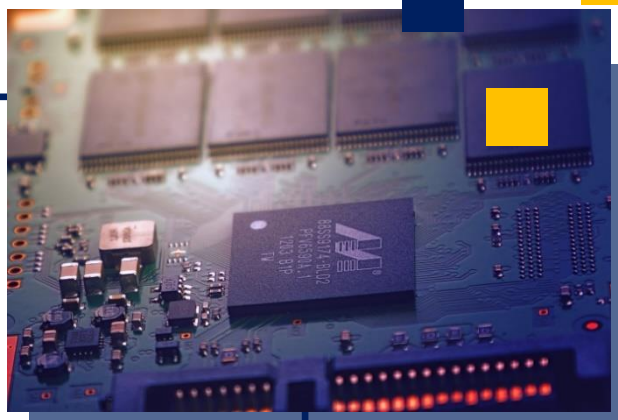
FiMVO
Suomen Lääkevarmennus

Letters of Announcement

On 12th July, we announced that EU Hub Release 1.5 had been deployed in the IQE environment.

In addition to the deployment of Release 1.5 in the IQE environment, the new release of the Arvato National Systems will include a timestamp change to comply with the UTC Zulu format. EMVO strongly recommends that all OBPs conduct IQE testing to ensure that call-backs are correctly received from these national systems.

To see the full Letter of Announcement and find further information: **https://bit.ly/2LpnrDh**



On 18th July, EMVO announced that a plan is in place to propagate all alerts received from the National Systems to OBPs (date of implementation to follow) as currently the EU Hub is not propagating all Level 5 alerts to OBPs which it is receiving from the National Systems.

For further information on the alerts that will be propagated: **https://bit.ly/32zFU56**

EVI updates

On 16th July, EMVO reported on an incident which occurred on 15th July, and which had affected the national systems of Austria, Belgium, Estonia, Finland, France, and Germany from 14:50 UTC (15th July) – 08:10 UTC (16th July). Due to a human error, the session tokens of these National Systems were incorrectly reset in the PRD environment. To prevent this incident from occurring again, a CAPA was raised immediately to improve the relevant internal processes and systems.

For further information: **https://bit.ly/2M3iGhQ**

Q&A

We have also published the updated version of the European Commission's Q&A document (V.15) on the Safety Features for Medicinal Products for Human Use.

To see the full document, please follow this link: **https://bit.ly/2Z2VGDi**

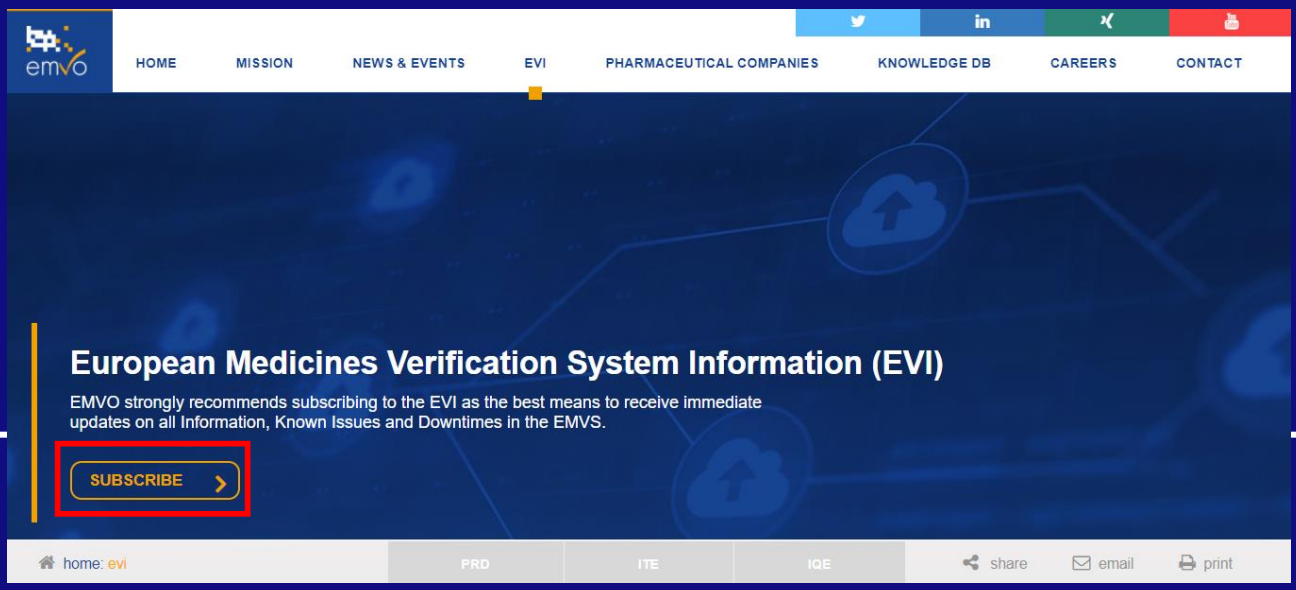
Open positions

We are currently growing our organisation to meet the needs of the Operational Phase of the EMVS and are looking to fill several positions.

To see the four open positions at EMVO:
https://emvo-medicines.eu/careers/

European Medicines Verification System Information (EVI)

We strongly encourage all interested parties to subscribe to notifications from the EVI tool on our website. This is the best way to receive technical updates related to the systems of the EMVS, with general information also being posted here alongside Known Issues and Downtimes.



EMVO's Helpdesk
Telephone number: + 372 611 90 44
E-mail address: helpdesk@emvo-medicines.eu

European Medicines Verification Organisation

Follow EMVO's activities via:
Our website
Twitter
LinkedIn